

III Remarks

**A. Rejection of Claims 46, 48–53, 55, 57–61 and 64
Under 35 U.S.C. § 102(b) as being Anticipated by
United States Patent No. 5,750,563 to Honda (“the ‘563 patent”)**

1. Reasons for Rejection

The Examiner's reasons for the rejection are as follows:

The '563 patent is drawn to a preparation comprising polyphenols, antimicrobial agents and lactic acid (abstract, col. 4, lin. 20–25). The composition comprises at least one gallic acid derivatives such as tannic acid; a flavonoid such as gossypetin and various extracts and essential oils such as camphor (col. 3, lin. 25–col. 4, lin. 26, claim 1). The components of the composition are present in concentrations from 0.1 to 20% (*ibid.*) These disclosures render the claims anticipated.

Examiner's Action, Paragraph 3.

**2. Comparison of Applicant's Claimed Invention
with the '563 Patent**

Applicant's invention as claimed in claim 46 is directed to an antimicrobial composition ***consisting essentially of*** at least one generally recognized as safe flavoring agent selected from polyphenol compounds and lactic acid, a physiologically acceptable salt thereof or hydrophilic acetate or hydrophilic aldehyde, the mixture containing no other generally recognized as safe flavored alcohols (emphasis added). As the other rejected claims, 48–53, 55, and 57–61 are either dependent upon claim 46 or upon a claim ultimately dependent upon claim 46, these claims also contain the limitations set forth in claim 46. Independent claim 64 recites the composition set forth in claim 46.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not ***materially*** affect the ***basic*** and ***novel*** characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551–52, 190 USPQ 461, 463 (CCPA 1976) (*emphasis in original*). (M.P.E.P. 2111.03).

The '563 patent is directed to a preparation for epidermis containing kojic acid and/or its derivative and at least one member selected from the group consisting of alcohols and polyphenols (See '563 patent Abstract and Summary of the Invention at Column 2, lines 15–24). Kojic acid has the chemical formula $C_6H_6O_4$. It is not a polyphenol. Nor is it lactic acid, which has the formula $C_3H_6O_3$. Applicant's composition, as claimed in claim 46, cannot include kojic acid as kojic acid would materially affect the basic and novel characteristics of Applicant's claimed composition. As the remaining rejected claims, 48–53, 55, 57–61 and 64 are all

dependent upon claim 46, or, as to claim 64, set forth the same limitations as referenced above for claim 46, these claims also cannot include kojic acid.

Moreover, the preparations disclosed in the '563 patent do not include lactic acid, which is an essential ingredient of Applicant's claimed composition. The only reference in the '563 patent to lactic acid is as an extract of culture liquor of lactic acid bacteria, *i.e.*, a bacteria that secretes lactic acid. As Applicant's antimicrobial composition is intended to be toxic to microbes such as bacteria, the lactic acid cannot be expected to survive in Applicant's claimed antimicrobial composition and, therefore, could not function as a source of lactic acid.

In summary, the compositions disclosed in the '563 patent differ from Applicant's claimed composition in disclosing as an essential ingredient, kojic acid, which is excluded from Applicant's claimed composition, and in not disclosing lactic acid, which is an essential ingredient in Applicant's claimed composition. The rejection is established only if all of the elements of an invention as stated in each of claims 46, 48–53, 55, 57–61 and 64 are identically set forth in the '563 patent. *Teleflex, Inc., v. Ficosa North America Corp.*, 299 F.3d 1313, 1355, 63 USPQ2d 1374, 1388 (Fed. Cir. 2002) ("As we have repeatedly stated, anticipation requires that each limitation of a claim must be found in a single reference.") Accordingly, as the compositions disclosed in the '563 patent do not include all of the elements of Applicant's claimed compositions, the rejection of claims 46, 48–53, 55, 57–61 and 64 under 35 U.S.C. § 102(b) as anticipated by the '563 patent, is untenable and must be withdrawn.

**B. Rejection of Claims 67–70 Under 35 U.S.C. § 102(b)
As Being Anticipated by United States Patent No. 5,322,689
to Hughes et al. (the "689 patent")**

1. Reasons for the Rejection

The Examiner's reasons for the rejection are as follows:

The '689 patent discloses a topical aromatic formulation comprising antibiotics, and carriers (col. 7, lin. 3–68). The carriers include humecatan/moisturizers like lactic acid, extracts such as camphor and eucalyptus oil and phenols such as thymol (examples). These disclosures render the claims anticipated.

Examiner's Action, Paragraph 5.

**2. Comparison of Applicant's Claimed Composition
and the Subject Matter Disclosed in the '689 Patent**

Applicant's composition as claimed in claim 67 is directed to ***an antimicrobial composition*** consisting essentially of B) a mixture free of benzyl alcohol and consisting

essentially of at least one generally recognized as safe flavoring agent selected from polyphenol compounds and comprising lactic acid and at least one phenol selected from a group of species of phenols. The mixture contains no other generally recognized as safe flavored alcohols. As claims 68–70 are dependent upon claim 67 or are dependent upon a claim ultimately dependent upon claim 67, claims 68–70 include the limitations set forth in claim 67.

The '689 patent is directed to topical aromatic releasing compositions substantially free from petrolatum and comprising a defined carboxylic copolymer and one or more volatile aromatic compounds selected from the group consisting of menthol, camphor and eucalyptus oil and mixtures thereof. (See '689 patent at column 2, lines 27–55).

The compositions disclosed in the Summary of the Invention of the '689 patent do not include polyphenol compounds, lactic acid or any of the species of phenols claimed in claim 67. Indeed, the essential ingredients in the '689 composition cannot be part of Applicant's composition as claimed in claims 67–70 as menthol, camphor and eucalyptus oil would materially affect the basic and novel characteristics of the composition. In fact, Applicant identifies camphor and eucalyptus as oils or extracts that can also be employed according to the invention. See Application at page 9, lines 3–10. As noted above, a rejection of claims 67–70 under 35 U.S.C. § 102(b) is established only if all of the elements of the invention as stated in each of claims 67–70 are identically set forth in the '689 patent. As the '689 patent does not set forth all of the elements of any of claims 67–70, the rejection of those claims under 35 U.S.C. § 102(b) as anticipated by the '689 patent is untenable and must be withdrawn.

**C. Rejection of Claims 56 and 65 Under 35 U.S.C. § 103(a)
as Being Unpatentable Over the Combined Disclosures of
the '563 Patent, United States Patent No. 5,879,683 to Hamilton-Miller
(the "'683 patent'") and United States Patent No. 5,461,075
to Carson et al. (the "'075 patent'")**

1. Reasons for the Rejection

The Examiner's reasons for the rejection are as follows:

As discussed above the '563 patent discloses an antimicrobial composition comprising polyphenols, and other active agents. The patent suggests the inclusion of extracts of an animal or vegetable origin but is silent to the specific extracts recited by the claims. However tea extracts (*Camellia sinensis*) have long been known for their antimicrobial properties. These properties are discussed in the '683 and '075 patents.

The '683 patent discloses an antimicrobial formulation comprising tea extracts (black, green or oolong) (col. 3, lin. 52–58).

These formulations are used to fight infections (abstract). One of ordinary skill would be motivated to include the polyphenols of '683 into the formulation of '563 in order to fight more microbial infections.

The '075 patent discloses antimicrobial emulsions comprising extracts and antimicrobial compounds (abstract). The extracts include essential oils including camphor orange oil and anise oil (col. 8, lin. 38–53). A skilled artisan would have been able to follow the suggestions [in] '563 to include vegetable and essential oils, and include the anise oil of '075 in order to add flavor and an aromatic effect.

A skilled artisan would have been motivated to include the extracts of both '683 and '075 into the formulation of '563 in order to improve the antimicrobial fighting effects and improve the flavor and aromatic properties of the composition. These combinations would have been made under the suggestion of '563 to include essential oils and plant/vegetable extracts into the formulation. It would have been obvious to an artisan of ordinary skill to combine these components with an expected result of a topical formulation with improved microbial fighting and aromatic properties.

Examiner's Action, Paragraphs 9–12.

**2. Comparison of Applicant's Claimed Subject Matter
with the Combination of References**

Applicant's claims 56 and 65 have been amended to be dependent upon claims 46 and 64, respectively. As noted above, the '564 reference did not anticipate claims 46 and 64 because the '564 patent does not disclose the presence of lactic acid in an antimicrobial composition, only lactic acid bacteria that cannot be expected to secrete lactic acid in an antimicrobial composition expected to be toxic to bacterial microbes. The '683 and '075 patents do not even mention lactic acid, let alone its use in antimicrobial compositions. Accordingly, as none of these references discloses the use of lactic acid in a form available for use in Applicant's claimed antimicrobial compositions, one skilled in the art cannot obtain Applicant's claimed compositions from combining the references. Accordingly, a rejection of claims 56 and 65 under 35 U.S.C. § 103(a) as unpatentable over the '564, '683 and '675 patents is untenable and should be withdrawn.

**D. Rejection of Claims 62, 63 and 66 Under 35 U.S.C. § 103(a)
as Being Unpatentable Over United States Patent No.
5,750,563 to Honda**

1. Reasons for the Rejection

The Examiner's reasons for the rejection are as follows:

As discussed above the '563 reference discloses a formulation comprising lactic acid, and polyphenols. The reference discloses the concentration of the polyphenols included but is silent [as] to the lactic acid concentration. However applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Examiner's Action, Paragraph 14.

**2. Comparison of Applicant's Claimed Invention
with the '563 Reference**

Claim 62 is directed to the antimicrobial composition of claim 46, wherein the polyphenol is selected from tannins, tannic acid or mixtures thereof. Claims 63 and 66 are dependent, respectively, upon claims 46 and 64. Accordingly, for the reasons set forth in Section A above, claims 62, 63 and 66 are directed to antimicrobial compositions consisting essentially of polyphenols and lactic acid, and with respect to claim 66, certain species of phenol.

For the reasons set forth above in Section A, the '563 patent does not exemplify, otherwise disclose or suggest to one of ordinary skill in the art the inclusion of lactic acid in Applicant's claimed antimicrobial composition because the composition would be expected to be toxic to the proposed bacterial source of the lactic acid.

Accordingly, the rejection of claims 62, 63 and 66 under 35 U.S.C. § 103(a) as unpatentable over the '563 patent should be withdrawn for the reasons stated in connection with the rejection of Applicant's claims 46, 48-53, 55, 57-61 and 64 over the same reference.

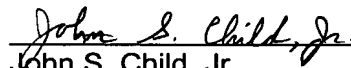
IV Conclusion

It is believed that the above Amendment and Remarks constitute a complete Response under 37 C.F.R. § 1.111 and that all grounds for objection stated in the Action have been adequately rebutted or overcome. A Notice of Allowance in the next Action is therefore requested. The examiner is requested to telephone the undersigned counsel if any matter that can be expected to be resolved in a telephone interview is believed to impede the allowance of the pending claims of Application Serial No. 09/743,883.

Respectfully submitted,

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Enclosures: Certificate of Mailing Under 37 C.F.R. § 1.8(a)
 Petition for Extension of Time Under 37 C.F.R. § 1.136(a)
 Authorization To Charge Deposit Account (original + 1 copy)
 Fee Transmittal for FY 2005 (original + 1 copy)
 Check in the amount of \$60.00
 Amendment and Response To United States Patent and Trademark Office
 Examiner's Action Under 37 C.F.R. § 1.111
 Return postcard

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